

May 16, 2008

Roger Citron

Dear Mr. Citron:

Thank you for your interest in LUVOX CR (fluvoxamine maleate) extended-release capsules.

LUVOX CR Capsules are indicated for the treatment of SAD, also known as social phobia, as defined in DSM-IV (LUVOX CR Prescribing Information, Jazz Pharmaceuticals, 2008). SAD is characterized by a marked and persistent fear of one or more social or performance situations in which the person is exposed to unfamiliar people or to possible scrutiny by others. Exposure to the feared situation almost invariably provokes anxiety, which may approach the intensity of a panic attack. The feared situations are avoided or endured with intense anxiety or distress. The avoidance, anxious anticipation, or distress in the feared situation(s) interferes significantly with the person's normal routine, occupational or academic functioning, or social activities or relationships, or there is marked distress about having the phobias. Lesser degrees of performance anxiety or shyness generally do not require psychopharmacological treatment.

LUVOX CR Capsules are indicated for the treatment of obsessions and compulsions in patients with obsessive compulsive disorder (OCD), as defined in the DSM-IV (LUVOX CR Prescribing Information, Jazz Pharmaceuticals, 2008). The obsessions or compulsions cause marked distress, are time-consuming, or significantly interfere with social or occupational functioning. Obsessive compulsive disorder is characterized by recurrent and persistent ideas, thoughts, impulses or images (obsessions) that are ego-dystonic and/or repetitive, purposeful, and intentional behaviors (compulsions) that are recognized by the person as excessive or unreasonable.

Per your request, please find enclosed the following information:

Luvox CR Formulary Dossier

If you would like additional assistance, please call 1-800-520-5568.

Sincerely,

Jazz Pharmaceuticals, Inc.

Catharine A. Rich, Pharm.D. Medical Information Department

Roger Citron May 16, 2008 Page 2

## **ENCLOSURES**

Luvox CR Package Insert

Luvox CR Formulary Dossier